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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,095	03/29/2001	Ming-Hui Wei	CL001202	2541

7590 06/02/2004

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,095	WEI ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, and 20-21 drawn to an isolated peptide comprising an amino acid sequence consisting of SEQ ID NO: 2, classifiable in class 530, subclass 350.

II. Claim 3, drawn to an isolated antibody that binds to a peptide of claim 2, classifiable in class 530, subclass 387.1.

III. Claims 4, 5, 6, 8, 9, 10, 11, and 22-23, drawn to an isolated nucleic acid comprising a nucleotide sequence consisting of a nucleotide sequence that encodes an amino acid sequence shown in SEQ ID NO: 2, classifiable in class 536, subclass 23.5.

IV. Claim 7, drawn to a transgenic non-human animal comprising the nucleic acid molecule of claim 5, classifiable in class 800, subclass 13.

V. Claim 12, drawn to a method of detecting the presence of any of the peptides of claim 2 in a sample, classifiable in class 435, subclass 4.

VI. Claim 13, drawn to a method of detecting the presence of a nucleic acid molecule of claim 5 in a sample, classifiable in class 435, subclass 6.

VII. Claims 14, 15, and 16, drawn to a method for identifying a modulator of an isolated peptide of claim 2, classifiable in class 435, subclass 7.1.

VIII. Claim 19, drawn to a method for identifying a modulator of the expression of a peptide of claim 2 comprising an expression vector that expresses the peptide, classifiable in class 435, subclass 7.21.

IX. Claim 17, drawn to a pharmaceutical composition comprising an agent, unclassifiable.

X. Claim 18, drawn to a method of treating a disease or condition in a subject mediated by a human proteases comprising administering an agent to the subject, unclassifiable.

The inventions are distinct, each from the other because of the following reasons:

The isolated peptide in Invention I, the antibody in Invention II, the isolated nucleic acid in Invention III, the transgenic non-human animal in Invention IV, the identification of a peptide in a sample in Invention V, the identification of a nucleic acid in a sample in Invention VI, the screening method in Invention VIII, the pharmaceutical agent in Invention IX, the method for treating a disease in Invention X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations and have different functions. The specification does not disclose that the inventions are capable of use together. The isolated peptide in Invention I, antibody in Invention II, or the isolated nucleic acid in Invention III, and the transgenic non-human animal in Invention IV are not required in the method set forth in Invention V, the method set forth in Invention VI or the method set forth in Invention VIII. The specification does not disclose a distinct chemical structure of an agent for the pharmaceutical

composition set forth in Invention IX or for use in the method set forth in Invention X. The difference between Inventions I, II, III, IV, V, VI, and VIII are further underscored by their different classification and independent search status.

The antibody in Invention II, the isolated nucleic acid in Invention III, the transgenic non-human animal in Invention IV, and the screening a modulator method in Invention VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation and have different functions. The antibody in Invention II, the isolated nucleic acid in Invention III, the transgenic non-human animal in Invention IV are not required in the method set forth in Invention VII. The specification does not disclose that the inventions are capable of use together. The differences between Inventions II, III, IV, and VII are further underscored by their different classification and independent search status.

Inventions V, VI, VII, VIII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that have a different mode of operation. The specification does not disclose that the inventions are capable as use together. The method in Invention VI has a different mode of operation than the methods in Inventions V, VII, VIII, and X. The isolated peptide used in the method of Invention VII is not required in Inventions V, VI, VIII, and X. The specification does not disclose a distinct chemical structure of an agent for

use in the method set forth in Invention X. The differences between Inventions V, VI, VII, and VIII are further underscored by their different classification and independent search status.

Invention I and Invention VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated peptide in Invention I can be used in materially different processes, e.g., making antibodies, peptide therapy. The differences between Inventions I and VII are further underscored by their different classification and independent search status.

Because these inventions are distinct for the reasons given above and the search required for each listed above Group is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER